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| EXAMINER |
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WOODALL, NICHOLAS W

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| ART UNIT | PAPER NUMBER |
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3733

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09/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/505,463 | Applicant(s) FANKHAUSER ET AL. | |
| | Examiner Nicholas Woodall | Art Unit 3733 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 21 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08/20/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>08/20/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on 07/06/2007.

Election/Restrictions

2. Applicant's election without traverse of Group I, directed to claims 1-21, in the reply filed on 07/06/2007 is acknowledged. Claims 22-26 have been canceled.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the marking bodies being arranged in a non-collinear manner and/or span a plane (claim 6), the marking bodies being cylindrical (claim 8), the marking bodies defining a conical tip (claim 9), and the pins having a concave end face (claim 13) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Regarding claim 6, drawings do not show all the possible combinations relating to the and/or statement, i.e. the marking bodies being arranged in a non-collinear manner or the marking bodies being arranged in a non-collinear manner and spanning a plane.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

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changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

4. Claim 1 is objected to because of the following informalities: Claim 1 states, ...wherein a magazine with the at least one marking body can be attached to a magazine retainer on one of the forceps limbs. The examiner believes that this part of the claim is functionally recited because the claim does not require the magazine to be attached to the magazine retainer. The language "...can be attached..." does not require the device to have the magazine attached to the magazine retainer, but the claim only requires the device be capable of having a magazine attached to a magazine retainer. The examiner will interpret the claims as the magazine being a required component of the device for examination purposes. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There exists an inconsistency between the language of claim 1 and that of the claim 7 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, lines 1, applicant recites "A device" with the at least one marking body being functionally recited, i.e. "for the implantation of at least one marking body...", thus indicating that the claim is directed to the subcombination, "A device". However, in claim 7, lines 1-2, applicant positively recites the marking body as part of the invention, i.e. "wherein the marking bodies are spherical.", thus indicating that the combination, a device and at least one marking body, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-21 will be considered as being drawn to the subcombination, a device.

There exists an inconsistency between the language of claim 1 and that of the claim 8 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, lines 1, applicant recites "A device" with the at least one marking body being functionally recited, i.e. "for the implantation of at least one marking body...", thus indicating that the claim is directed to the subcombination, "A device". However, in claim 7, lines 1-2, applicant positively recites the marking body as part of the invention,

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i.e. "wherein the marking bodies are cylindrical.", thus indicating that the combination, a device and at least one marking body, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-21 will be considered as being drawn to the subcombination, a device.

There exists an inconsistency between the language of claim 1 and that of the claim 9 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 1, lines 1, applicant recites "A device" with the at least one marking body being functionally recited, i.e. "for the implantation of at least one marking body...", thus indicating that the claim is directed to the subcombination, "A device". However, in claim 9, lines 1-2, applicant positively recites the marking body as part of the invention, i.e. "wherein the marking bodies define a conical tip...", thus indicating that the combination, a device and at least one marking body, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 1-21 will be considered as being drawn to the subcombination, a device.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Wyatt (U.S. Patent 3,669,104).

Regarding claim 1, Wyatt discloses a device in the form of a forceps comprising a medial handle (12), a lateral handle (68), a medial limb (44), a lateral limb (54), a magazine retainer (24) on one of the limbs, and a magazine (22) with at least one marking body capable of being attached to the magazine retainer. Regarding claim 2, Wyatt discloses a device comprising at least two marking bodies in the magazine. Regarding claim 3, Wyatt discloses a device comprising a spring element (74) acting on the medial handle and the lateral handle and a four-lever articulated joint capable of displacing the medial limb and the lateral limb in a mutually parallel manner. The examiner believes the ends of the limbs both move laterally along mutually parallel paths during the use of the device. Regarding claim 4, Wyatt discloses a device wherein the magazine defines boreholes and the marking bodies are arranged in the boreholes. Regarding claim 5, Wyatt discloses a device wherein the boreholes of the magazine are arranged in several rows. Regarding claim 6, Wyatt discloses a device wherein the marking bodies are arranged in a non-collinear manner and/or span a plane.

9. Claims 1, 3, 7-9, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Bauer (U.S. Patent 5,540,240).

Regarding claim 1, Bauer discloses a device comprising a medial forceps handle, a lateral forceps handle, a medial forceps limb, a lateral forceps limb, a magazine retainer on one of the forceps limbs, and a magazine (134) capable of being attached to the magazine retainer (18). Regarding claims 3 and 21, Bauer discloses a device comprising a spring element (124), i.e. two plate springs, acting on the forceps handles and a four-lever articulated joint capable of displacing the forceps limbs in a mutually parallel manner. Regarding claim 7, Bauer discloses a device capable of being used with marking bodies having a spherical shape. Regarding claim 8, Bauer discloses a device capable of being used with marking bodies having a cylindrical shape. Regarding claim 9, Bauer discloses a device capable of being used with marking bodies defining a conical tip with a conical angle between 30 and 60 degrees.

10. Claims 1, 2, 4, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Mallina (U.S. Patent 3,489,330).

Regarding claim 1, Mallina discloses a device comprising a medial forceps handle, a lateral forceps handle, a medial forceps limb, a lateral forceps limb, a magazine retainer on one of the forceps limbs, and a magazine (28) capable of being attached to the magazine retainer (32). Regarding claim 2, Mallina discloses a device wherein the magazine comprises two marking bodies. Regarding claim 4, Mallina discloses a device wherein the magazine defines boreholes and the marking bodies are arranged in the boreholes. The examiner is interpreting the rounded ends of the slot in

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the magazine as the bore holes. Regarding claim 16, Mallina discloses a device wherein the magazine comprises a structurally-rigid material capable of sterilization (column 5 lines 50-53).

11. Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Fleischer (U.S. Patent 4,241,861).

Regarding claim 1, Fleischer discloses a device comprising a medial forceps handle, a lateral forceps handle, a medial forceps limb, a lateral forceps limb, a magazine retainer on one of the forceps limbs, and a magazine (17) capable of being attached to the magazine retainer (18). Regarding claim 2, Fleischer discloses a device wherein the magazine comprises two marking bodies. Regarding claim 4, Fleischer discloses a device wherein the magazine defines boreholes and the marking bodies are arranged in the boreholes. The examiner is interpreting the rounded ends of the slots in the magazine as the bore holes. Regarding claim 5, Fleischer discloses a device wherein the boreholes of the magazine are arranged in several rows. Regarding claim 6, Fleischer discloses a device wherein the marking bodies are arranged in a non-collinear manner and/or span a plane.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 7, 8, 11-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt (U.S. Patent 3,669,104).

Regarding claims 7, 8 and 13, Wyatt discloses the invention as claimed except for the marking bodies having a spherical shape (claim 7), the marking bodies having a cylindrical shape (claim 8), and the pin having a concave face (claim 13). It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to manufacture the device of Wyatt wherein the marking bodies had a spherical or cylindrical shape and the pin having a concave face, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a marking body and a pin. In re Dailey and Eilers, 149 USPQ 47 (1966).

Regarding claims 11, 12, and 14, Wyatt discloses a device comprising a magazine indirectly connected, which the examiner is interpreting as being provided onto, the lateral limb and a pin that extends in the direction of the lateral limb arranged on the medial limb. Regarding claim 12, Wyatt discloses a device wherein the pin is arranged in mutual alignment with the boreholes of the magazine. Regarding claim 14, Wyatt discloses a device wherein the pins are pressed into the boreholes pressing the marking bodies out of the boreholes and into tissue, such as bone. Wyatt fails to disclose the device comprising a plurality of pins (claim 11). It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt including a plurality of pins, since it has been held that mere

duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claim 16, Wyatt discloses the invention as claimed except for the magazine comprising a structurally rigid material capable of being sterilized. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt from a structurally rigid material capable of being sterilized, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

14. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt (U.S. Patent 3,669,104) in view of Cafferata (U.S. Patent 6,689,121).

Regarding claim 9, Wyatt discloses the invention as claimed except for the marking body having a conical shape. Cafferata teaches a device comprising marking bodies having a conical shape in order to facilitate the insertion of the marking bodies. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt with marking bodies having a conical shape in view of Cafferata in order to facilitate insertion of the marking bodies.

Further regarding claim 9, the combination of Wyatt and Cafferata disclose the invention as claimed except for the marking bodies having a conical tip with an angle between 30 degrees and 60 degrees. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt modified by Cafferata with marking bodies having a conical tip with an angle

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between 30 degrees and 60 degrees, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt (U.S. Patent 3,669,104) in view of Parsons (U.S. Patent 4,827,493).

Regarding claim 10, Wyatt discloses the invention as claimed except for marking bodies comprising a material that produces a contrast relative to bone. Parsons teaches a device comprising marking bodies comprising a material that produces a contrast relative to bone in order to provide good X-ray analysis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt wherein the marking bodies comprise a material that produces a contrast relative to bone in view of Parsons in order to provide good X-ray analysis.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wyatt (U.S. Patent 3,669,104) in view of Daly (U.S. Patent 6,090,631).

Regarding claim 15, Wyatt discloses the invention as claimed except for the magazine with the marking bodies are packed in a sterile manner. Daly teaches a device comprising a magazine with marking bodies that are packed in a sterile manner in order to prevent infection in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Wyatt wherein the magazine with the marking bodies are packed in a sterile manner in view of Daly in order to prevent infection in the patient.

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17. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer (U.S. Patent 5, 540, 240).

Regarding claim 16, Bauer discloses the invention as claimed except for the magazine comprising a structurally rigid material capable of being sterilized. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Bauer from a structurally rigid material capable of being sterilized, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischer (U.S. Patent 4,241,861).

Regarding claim 16, Fleischer discloses the invention as claimed except for the magazine comprising a structurally rigid material capable of being sterilized. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Fleischer from a structurally rigid material capable of being sterilized, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mallina (U.S. Patent 3,489,330).

Regarding claim 10, Mallina discloses the invention as claimed except for the marking bodies being made from a material that produces a contrast relative to bone. It

would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Mallina wherein the marking bodies are made from a material that produces a contrast relative to bone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

20. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer (U.S. Patent 5,540,240) in view of Daly (U.S. Patent 6,090,631).

Regarding claim 15, Bauer discloses the invention as claimed except for the magazine with the marking bodies are packed in a sterile manner. Daly teaches a device comprising a magazine with marking bodies that are packed in a sterile manner in order to prevent infection in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Bauer wherein the magazine with the marking bodies are packed in a sterile manner in view of Daly in order to prevent infection in the patient.

21. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mallina (U.S. Patent 3,498,330) in view of Daly (U.S. Patent 6,090,131).

Regarding claim 15, Mallina discloses the invention as claimed except for the magazine with the marking bodies are packed in a sterile manner. Daly teaches a device comprising a magazine with marking bodies that are packed in a sterile manner in order to prevent infection in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of

Mallina wherein the magazine with the marking bodies are packed in a sterile manner in view of Daly in order to prevent infection in the patient.

22. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischer (U.S. Patent 4,241,861) in view of Daly (U.S. Patent 6,090,131).

Regarding claim 15, Fleischer discloses the invention as claimed except for the magazine with the marking bodies are packed in a sterile manner. Daly teaches a device comprising a magazine with marking bodies that are packed in a sterile manner in order to prevent infection in the patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Fleischer wherein the magazine with the marking bodies are packed in a sterile manner in view of Daly in order to prevent infection in the patient.

Allowable Subject Matter

23. Claims 17-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for cited references the examiner felt were relevant to the application.

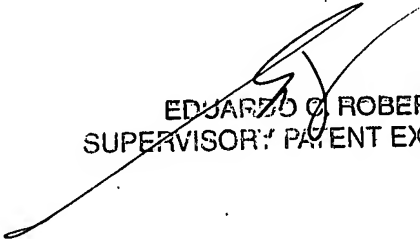
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicholas Woodall whose telephone number is 571-272-5204. The examiner can normally be reached on Monday to Friday 8:00 to 5:30 EST..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWWW



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